REMARKS

Applicants have carefully reviewed the Final Office Action dated December 31, 2003. Claims 24-31 have been canceled; claims 10, 16-20, 22 and 23 are withdrawn, and claims 1-9, 11-15, 21, and 24-31 are rejected. Claims 1-23 remain pending.

Applicants thank the Examiner for granting a telephone interview with their representative on February 18, 2004.

The Examiner continues to reject claims 1-9, 11-15, 21 and 24-31 under 35 U.S.C. 35 §102(e) as being anticipated by Heck, U.S. Patent No. 6,083,207. The rejection is based on the assertion of the Examiner that the Heck patent discloses a hemostasis valve that compresses a device as that device is being passed through the hemostasis valve body. Applicants continue to traverse this rejection.

Based on the Examiner's comments and arguments in the previous Office Action, mailed June 30, 2003, it appeared that the Examiner did not understand the way in which a conventional hemostasis valve operates. In response, Applicants provided the Examiner with a detailed description, including medical textbook entries, of how conventional hemostasis valves function. The Examiner appears not to have considered this discussion, based on the statement, on page 6 of the Office Action, that the Heck hemostasis valve "operates differently." The Examiner, however, does not indicate how Heck is interpreted as operating differently.

The Examiner's attention is directed to column 9, lines 31-32 of Heck where the disclosed device is specifically described as "the partitioned hemostasis valve (14) acts like a conventional hemostasis valve." In view of this direct statement in Heck, one of ordinary skill in the art would interpret Heck as operating as a conventional hemostasis valve in preventing blood flow **around** the device inserted through the valve. As a further indication of the fact that the device of Heck functions by sealing around whatever is inserted through the valve, the Examiner's attention is

directed to column 5, lines 33-35, where Heck describes the valve as configured to receive a dilator, catheter, pacemaker lead or other medical device. If the Heck valve can be used either with a catheter, which has a lumen, and a pacemaker lead, which one of ordinary skill in the art knows does not have a lumen, then Heck cannot possibly be construed to have means for compressing a valve sleeve for restricting fluid flow through the valve sleeve lumen, as is recited in the claims.

The Examiner repeatedly cites column 2, lines 33-36 of Heck as support for the device limiting blood flow during the introduction of a medical device through the sheath. The Examiner also states, on page 7 of the Office Action, that "the valve that Heck discloses must pinch the medical device in order to prevent blood flow." The device of Heck functions as a conventional hemostasis valve, and Heck is describing, in column 2, the function of a conventional hemostasis valve in preventing blood flow **around** the device inserted through the valve. There is absolutely no disclosure or suggestion in Heck of restricting blood flow **through** a device inserted into the valve.

Each of the present independent claims contains the limitation that the device contains a structure that performs this function. There is no structure in the Heck device that performs this function. The Examiner asserts that the neck opening (52) and lips (56) of the Heck device "compress" a device such as a catheter that is placed in the valve. This interpretation is contrary to the specific teachings in Heck. In column 5, lines 53-57, Heck states that the sections of the valve are "formed from a conventional hemostasis valve material, such as a pliant, resilient rubber, such as silicon rubber, latex rubber or a foamed rubber." Heck goes on to describe the outside wall of the valve sections as providing "space for lips (56) to separate without excessive force being applied, as the medical device passes through the lips (56)." See column 6, lines 44-

46. Heck also describes the outside wall sections as serving to "prevent the lips from opening when no pressure is place on them by the medical device." See column 6, lines 60-62. These passages clearly describe a hemostasis valve with pliant valve sections that are deformed or compressed by the device such that they form a seal around the device. Thus, the device disclosed by Heck is structurally and functionally different from the claimed device.

With respect to independent claim 1, the claimed valve includes a compressible valve sleeve with a lumen, and a means for compressing that valve sleeve lumen to the extent that fluid flow through the lumen is restricted. The device of Heck fails to teach a structure that performs this function. The Examiner asserts that the lips (56) of the Heck valve "compress" a medical device such as a catheter that is placed between them. Applicants submit that there is no teaching or suggestion in Heck that the valve lips are structured such that they would or could compress a catheter to the extent that fluid flow through it was restricted. The entire disclosure of Heck is directed to the device acting like a conventional hemostasis valve, which forms a seal around the device within the valve. Additionally, because Heck teaches the valve as suitable for holding a pacemaker lead, one of skill in the art would understand that the Heck valve does not compress the device within the valve, but rather the valve itself is compressed or deformed to form a seal around the device.

The Examiner asserts, in the response to Applicants' previous arguments, that "compressible" is defined as capable of being compressed, and the catheter or other medical device described by Heck is considered "capable of being compressed". The Examiner also states that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to be patentably distinguished.

Applicants submit that the claimed device does contain structural differences that distinguish it over the device of Heck. The independent claims recite the limitation that the valve has a means for compressing the valve sleeve for restricting fluid flow through the valve sleeve lumen. The claimed device thus has a structural feature that compresses the valve sleeve sufficiently to restrict fluid flow through it. While a catheter or other medical device may be capable of being compressed to some degree, there is absolutely no teaching or suggestion in Heck that the disclosed valve has a structure that would or could actually compress a catheter to the degree that fluid flow through it was restricted. Thus, Heck fails to teach a structure of the claimed device and, therefore, cannot be considered to anticipate the claims.

For the reasons set forth above, Heck fails to teach the structural features of the claimed invention and thus cannot be deemed to anticipate the claims. Withdrawal of the rejection and reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
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By their Attorney,

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